# NAMIBIA MEDICINES REGULATORY COUNCIL

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## PUBLIC NOTICE 008/2021

### APPROVED ANTIGEN RAPID DIAGNOSTIC KIT FOR USE IN NAMIBIA

The Namibia Medicines Regulatory Council (NMRC) hereby lists Antigen Rapid Diagnostic Test Kits (Ag-RDT) that have met all regulatory requirements and have therefore received approval for use under defined conditions.

| S/N | APPROVED NAME OF MEDICAL DIVICE(S) | MANUFACTURER AND SITE ADDRESS |
|---|---|---|
| 1. | SD Biosensor Standard Q COVID-19 Antigen Kit | SD Biosensor, Inc<br>74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheogju-si, Chungcheongbuk-do 28161, KOREA |
| 2. | PANBIO™ COVID-19 Antigen Kit | Abbott Rapid Diagnostic Jena GmbH,<br>Orlaweg 1, 07743 Jena, Germany |
| 3. | Green Spring SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold) | Shenzhen Lvshiyuan<br>Biotechnology Co., Ltd, China |
| 4. | Lumira Dx SARS-CoV-2 Antigen Test | LumiraDx UK Ltd<br>Dumyat Business Park, United Kingdom |
| 5. | SARS-COV-2 Rapid Antigen Test (Roche) | SD Biosensor, Inc<br>74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheogju-si, Chungcheongbuk-do 28161, KOREA |

**Please also note that the Council has updated the *Regulatory Requirements for the Sale, Distribution and Use of COVID-19 Rapid Antigen Rapid Diagnostic Test Kits* in the *Public Notice 004/21*, dated 21 June 2021.**

## The following are the conditions for use of the approved test kits

1. The rapid test kits should **ONLY** be supplied to and used in health facilities (as defined in the Health Facility Act No 36 of 1994) or institutions where medical personnel certified is/are present to perform the test. The supplier should therefore provide the NMRC with the list of recipients of the test kits.
2. It is the responsibility of the supplier to ensure that the medical personnel to be performing the tests have received training on specimen collection, Ag-RDT testing (MoHSS algorithm) and biosafety measures. Therefore, only certified users are permitted to perform the tests.
3. Medical personnel conducting tests should adhere to the most recent Ministry of Health and Social Services Guidance on Rapid Diagnostic Testing for Covid-19 Response.
4. Medical Personnel (end-users of the test kits) **MUST** report all their test results to the Ministry of Health and Social Services.
5. Medical personnel (end-users of the test kits) should provide the NMRC with an activity report after one month of use which includes use of the kits, operational or diagnostic challenges or successes.
6. End-users, distributors and/or manufacturers must report any adverse event or product problem or suspected falsified product or suspected unapproved devices to NMRC.
7. Authorization for any Ag-RDT may be revoked if the condition(s) under which it was issued are not met or if new evidence that do not support use emerges.

Yours sincerely,

**MR JOHANNES ǂGAESEB**
**REGISTRAR OF MEDICINES**